

PTO/55/03A (02-03)

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 17

Application Number	10/669,250
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (U.S. Pat.)			
leu	1	US- 4,021,472 A	05/1977	Fujii et al.	
	2	US- 4,051,842 A	10/1977	Hazel et al.	
	3	US- 4,140,122 A	02/1979	Kuhl et al.	
	4	US- 4,224,342 A	09/1980	Fujii et al.	
	5	US- 4,283,418 A	08/1981	Fuji et al.	
	6	US- 4,310,533 A	01/1982	Uegai et al.	
	7	US- 4,383,529 A	05/1983	Webster	
	8	US- 4,629,567 A	12/1986	Bollen et al.	
	9	US- 4,657,763 A	04/1987	Finkelstein	
	10	US- 4,668,504 A	05/1987	Kahan et al.	
	11	US- 4,711,848 A	12/1987	Insley et al.	
	12	US- 4,713,224 A	12/1987	Tamhankar et al.	
	13	US- 4,732,973 A	03/1988	Barr et al.	
	14	US- 4,760,130 A	07/1988	Thompson et al.	
	15	US- 4,788,603 A	11/1988	Fujimura et al.	
	16	US- 4,829,052 A	05/1989	Glover et al.	
	17	US- 4,839,283 A	06/1989	Kawasaki et al.	
	18	US- 4,843,094 A	06/1989	Imaki et al.	
lee	19	US- 4,889,723 A	12/1989	Kim et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>5</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
le	20	WO 94/07525	04/1994			
I	21	WO 95/28422	10/1995			
	22	WO 95/34538	12/1995			
	23	WO 96/12021	04/1996			
lee	24	WO 96/14067	05/1996			
	25	WO 97/03679	02/1997			

Examiner Signature *leu*Date  
Considered

1-3-06

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Application Number	10/669,250
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

Sheet 2 of 17

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W	26	US- 4,931,279 A	06/1990	Bawa et al.	
	27	US- 4,963,654 A	10/1990	Katunuma	
	28	US- 5,004,612 A	04/1991	Kim et al.	
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	32	US- 5,166,134 A	11/1992	Lezdey et al.	
	33	US- 5,175,253 A	12/1992	Fallon et al.	
	34	US- 5,214,191 A	05/1993	Kirschenheuter et al	
	35	US- 5,216,022 A	06/1993	Oleksyszyn et al.	
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	37	US- 5,247,084 A	09/1993	Imaki et al.	
	38	US- 5,399,346 A	03/1995	Anderson et al.	
	39	US- 5,416,191	05/1995	Cheronis et al.	
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	44	US- 5,478,727 A	12/1995	Roizman et al.	

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W	45	WO 97/09346	03/1997			
	46	WO 97/09347	03/1997			
	47	WO 97/10222	03/1997			
	48	WO 97/10231	03/1997			
	49	WO 97/21690	06/1997			
	50	WO 97/24339	07/1997			

Examiner  
Signature

W. W. W. W.

Date  
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1-3-06

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First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

Sheet 3 of 17

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W	51	US- 5,486,470 A	01/1996	Darke et al.	
	52	US- 5,489,593 A	02/1996	Palmer et al.	
	53	US- 5,504,094 A	04/1996	Nakane et al.	
	54	US- 5,514,653 A	05/1996	Perlmutter	
	55	US- 5,514,713 A	05/1996	Nakai et al.	
	56	US- 5,529,920 A	06/1996	Cole et al.	
	57	US- 5,532,215 A	07/1996	Lezdey et al.	
	58	US- 5,565,334 A	10/1996	Kufe et al.	
	59	US- 5,567,682 A	10/1996	Pert	
	60	US- 5,593,858 A	01/1997	Fleer et al.	
	61	US- 5,604,201 A	02/1997	Thomas et al.	
	62	US- 5,610,140 A	03/1997	Goodfellow et al.	
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	64	US- 5,614,555 A	03/1997	Nakai et al.	
	65	US- 5,616,693 A	04/1997	Hwang et al.	
	66	US- 5,618,792 A	04/1997	Gyorkos et al.	
	67	US- 5,622,984 A	04/1997	Nakai et al.	
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W	70	WO 97/31937	09/1997			
	71	WO 97/33996	09/1997			
	72	WO 97/37969	10/1997			
	73	WO 97/45402	12/1997			
	74	WO 97/48706	12/1997			
W	75	WO 97/49679	12/1997			

Examiner Signature	<i>W. Collette</i>	Date Considered	1-3-06
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**INFORMATION DISCLOSURE  
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Sheet 4 of 17

**Complete if Known**

Application Number	10/669,250
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

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100	76	US- 5,663,416 A	09/1997	Kirschenheuter et al	
	77	US- 5,665,589 A	09/1997	Harris et al.	
	78	US- 5,700,779 A	12/1997	Goodfellow et al.	
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	80	US- 5,712,117 A	01/1998	Sprecher	
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	83	US- 5,759,548 A	06/1998	Bathurst et al.	
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	86	US- 5,801,148 A	09/1998	Gyorkos et al.	
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	90	US- 5,817,484 A	10/1998	Yu et al.	
	91	US- 5,834,431 A	11/1998	Stewart et al.	
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100	94	US- 5,861,299 A	01/1999	Archibald et al.	

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100	95	WO 98/06417	02/1998			
	96	WO 98/09206	03/1998			
	97	WO 98/20034	05/1998			
	98	WO 98/21186	05/1998			
100	99	WO 98/22098	05/1998			
	100	WO 98/22619	05/1998			

Examiner Signature	<i>W. C. Lee</i>	Date Considered	1-3-06
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	101	US- 5,861,380 A	01/1999	Gyorkos et al.	
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	225	US- 5,314,910 A	05/1994	Kirschenheuter et al	
	226	US- 5,376,655 A	12/1994	Imaki et al.	
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	112	WO 98/23565	06/1998			
	113	WO 98/24806	06/1998			
	114	WO 98/46597	10/1998			
	115	WO 98/49190	11/1998			
	116	WO 98/50342	11/1998			
	117	WO 98/50420	11/1998			

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JW	118	WO 98/56821	12/1998			
	119	WO 97/41231	08/1999			
	120	WO 99/43308	09/1999			
	121	WO 00/52034	09/2000			

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Sheet	7	of	17

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
W	122	Aoki H, Akaiki T, Abe K, Kuroda M, Arai S, Okamura R, Negi A, Maeda H. Antiviral effect of oryzacystatin, a proteinase inhibitor in rice, against herpes simplex virus 1 in vitro and in vivo. Antimicrob Agents Chemother Apr. 1995; 39(4):846-9.	
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		Application Number	10/669,250		
		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
		Art Unit	1645		
		Examiner Name	Not Yet Assigned		
Sheet	8	of	17	Attorney Docket Number	330310.00103

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
[Signature]	132	Flaitz CM, Hicks MJ. "Molecular piracy: the viral link to carcinogenesis." Oral Oncol Nov. 1998;34(6):448-53.	
	133	Griffin, William C., "Calculation of HLB Values of Non-Ionic Sufactants", [H. L. B.--The Hydrophilic-Lipophilic Balance], J. Soc. Cos. Met. Chem., vol. 5, p. 249 (1954).	
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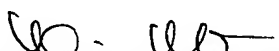
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		Application Number	10/669,250		
		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
		Art Unit	1645		
		Examiner Name	Not Yet Assigned		
Sheet	9	of	17	Attorney Docket Number	330310.00103

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le	142	Meylan et al., "HIV infectivity is not augmented by treatment with trypsin, Factor Xa or human mast-cell tryptase", AIDS, 6(1):128-30 (1992).	
f	143	Miranda et al., "Isolation of the human PC6 gene encoding the putative host protease for HIV-1 gp160 processing in CD4+ T lymphocytes", Proc Natl Acad Sci U S A, 93(15):7695-7700 (1996).	
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Substitute for form 1442-PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	10/669,250
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

Sheet 10 of 17

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le	152	Cilberto et al., 1985, Cell, 41:531-540.	
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		Application Number	10/669,250		
		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
		Art Unit	1645		
		Examiner Name	Not Yet Assigned		
Sheet	11	of	17	Attorney Docket Number	330310.00103

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le	162	Nathan, C. in FASEB J. 1992, 6, 3501.	
	163	Rehman, A. et al. in Br J Pharmacol, 1997, 122, 1702.	
	164	Pryor, W. A. et al., in Chem Biol Interact 1985, 54, 171.	
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le	172	Schini et al. in Circ Res 1994, 74, 24.	
f	173	Meki, A. R. et al. in Toxicon 1998, 36, 18519.	
	174	Popko B. and Baerwald, K. D. in Neurochem Res 1999, 24, 331.	
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	176	Sambrook, Fritsch & Maniatis, Molecular Cloning: A Laboratory Manual, Second Edition 1989, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, N.Y.	
	177	Remington's Pharmaceutical Sciences, 1990, p. 1519-1675, Gennaro, A.R., ed., Mack Publishing Company, Easton, PA.	
	178	Langer, R., Nature, 1998, 392, 5.	
	179	Budavari, Susan (Editor), "The Merck Index", An Encyclopedia of Chemicals, Drugs, and Biologicals; Merck & Co., Inc., 11th edition.	
	180	Merrifield, R.B., "Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide", 1963, J. Am. Chem. Soc., (85):2149.	
le	181	Animal Cell Culture, R.I. Freshney, ed. 1986, IRL Press, Oxford.	

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		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
		Art Unit	1645		
		Examiner Name	Not Yet Assigned		
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lc	182	Scharpe et al., "Protease and their inhibitors: today and tomorrow", 1991, Biochimie, 73(1):121-126.	
	183	Kido et al., "A novel membrane-bound serine esterase in human T4+ lymphocytes immunologically reactive with antibody inhibiting syncytia induced by HIV-1. Purification and characterization", J Biol Chem., 1990, 265(35):21979-85.	
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		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
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le	201	Kennedy et al., "Submandibular salivary proteases: lack of a role in anti-HIV activity", 1998, J Dent Res, 77(7):1515-9.	

Examiner Signature		Date Considered	1-3-06
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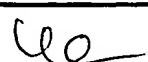
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		Application Number	10/669,250		
		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
		Art Unit	1645		
		Examiner Name	Not Yet Assigned		
Sheet	15	of	17	Attorney Docket Number	330310.00103

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
16	202	Premack, B.A. et al., "Chemokine Receptors: Gateways to Inflammation and Infection", 1996, Nature Medicine 2:1174-1178.		
	203	Zhirnov O.P. et al., "Antiviral activity of proteinase inhibitors in cultured cells infected with alpha-viruses", Mol Gen Mikrobiol Virusol, 1985, (12):30-6.		
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	207	Sharpstone D. et al., "Faecal alpha 1 antitrypsin as a marker of gastrointestinal disease in HIV antibody positive individuals", Gut, 1996, 38(2):206-10.		
	208	Patel et al., "The Role of Protease Drug During Apoptosis", 1996, FASEB J, 10(5):587-597.		
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		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
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(6)	212	Ooka, T., et al., "Protective effects of human urinary trypsin inhibitor against trypsin-induced relaxation in rat aorta", Crit care Med, 1996, 24(11): 1903-1907.	
	213	Novradovsky, A., et al., "Endothelial Nitric Oxide Synthase as a Potential Susceptibility Gene in the Pathogenesis of Emphysema in alpha1-Antitrypsin Deficiency", 1999, Am J Respir Cell Mol Biol, 1;20(3):441-447.	
	214	Cordiali Fei et al., "Behavior of several 'progression markers' during the HIV-Ab seroconversion period. Comparison with later stages", 1992, J Biol Regul Homeost Agents, 6(2):57-64).	
	215	Lima et al., "Mucosal injury and disruption of intestinal barrier function in HIV-infected individuals with and without diarrhea and cryptosporidiosis in northeast Brazil". 1997, Am J Gastroenterol, 92(10):1861-6.	
	216	Banfi et al., "Tumor-associated trypsin inhibitor in induced and acquired immunodeficiency. Studies on transplanted and HIV-infected patients", 1991, Scand J Clin Lab Invest 51, Suppl, 207:55-8.	
	217	Deam et al., "Alpha 1-antitrypsin phenotypes in homosexual men", 1989, Pathology, 21(2):91-2.	
	218	Pezzilli et al., "Serum pancreatic enzymes in HIV-seropositive patients", Dig Dis Sci, 1992, 37(2):286-8.	
	219	Tang et al., "Inactivation of HIV-1 by trypsin and its use in demonstrating specific virus infection of cells", 1991, J Virol Methods, 33(1-2):39-46.	
	220	Glozman, "Immunologic functions of enzyme therapy of patients with orchiepidymitis", 1990, Antibiot. Khimioter, 35(7):50-52.	
(6)	221	Franzusoff, et al., "Biochemical and genetic definition of the cellular protease required for HIV-1 gp160 processing", 1995, J Biol Chem, 270(7):3154-9).	

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W	222	Gu et al., "Furin is important but not essential for the proteolytic maturation of gp160 of HIV-1", FEBS Lett. 1995, 365(1):95-7.	
W	223	Bukrinskaia A.G., "Suppression of rotavirus SA-11 reproduction by protease inhibitors in cell culture", Vopr Virusol, 1987, 32(1):71-4.	

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